Policy for Reimbursement for Human Papilloma Virus Testing, Liquid-Based Pap Technology, and Conventional Pap tests

This policy addresses three policy changes for the Women's Health Connection (WHC) Program as they relate to cervical cancer screening. The changes relate to testing for the Human Papilloma Virus (HPV), reimbursement for liquid-based Pap tests, and the appropriate interval for Pap tests for women with consecutive normal Pap tests.

Effective June 30, 2007, the WHC Program will implement the following changes:

- Reimbursement will be allowed for **limited** HPV Deoxyribonucleic acid (DNA) (High-Risk), testing.
- Reimbursement will be allowed for liquid-based cervical cytology (Pap tests) on a biennial basis (every two years) or once every 3 years once the woman has had three consecutive normal, documented tests within a 60-month period.
- Reimbursement for conventional Pap tests shall be once every three years once the woman has had three consecutive normal Pap tests documented within a 60-month period.

HPV DNA Testing

The WHC Program will reimburse for HPV DNA (High-Risk) testing for the management of women with atypical squamous cells of undetermined significance (ASC-US) results from a screening Pap test or for surveillance at one year following a low-grade squamous intraepithelial lesions (LSIL) Pap test without evidence of cervical intraepithelial neoplasia (CIN) on colposcopy-directed biopsy for eligible women.

The approved Physicians' Current Procedural Terminology (CPT) code and its associated rate is:

87621	Hybrid Capture II from Digene-HPV Test (High-Risk Typing, only)	$49.04

Criteria

This policy follows the American Society of Colposcopy and Cytopathology (ASCCP) 2001 Consensus Conference on Management of Abnormal Cytology Results published guidelines.

Atypical Squamous Cells of Undetermined Significance (ASC-US)

When indicated, it is appropriate to perform HPV DNA testing, and this test is reimbursable for the management of ASC-US Pap test results. After performing an HPV DNA test, the recommended follow up is:

- HPV negative for high-risk types, repeat a screening Pap test at the appropriate interval as determined by the type of Pap test.
- HPV positive for high-risk types, proceed to colposcopy. Post colposcopy if:
  - Cervical biopsy correlates but **no** CIN/cancer, repeat of Pap test is recommended at six and twelve months **or** HPV DNA testing at twelve months.
  - Cervical biopsy confirms CIN/cancer, manage according to ASCCP guidelines.

Low-grade Squamous Intraepithelial Lesions (LSIL):
When indicated, it is appropriate to perform HPV DNA testing, and this test is reimbursable for the management of an LSIL Pap test for surveillance one year following the LSIL Pap test and when a woman has had a satisfactory colposcopy with a cervical biopsy without evidence of CIN. After performing an HPV DNA test, the recommended follow up is:

- HPV positive for high-risk types, repeat colposcopy.
- HPV negative for high-risk types, recommend 12 month screening or at clinician's discretion.

When the post diagnostic workup monitoring is complete, the clinician should return the client to the appropriate screening schedule as outlined in this policy.

Liquid-Based Technologies (Pap tests)
In accordance with the schedule designated in this policy, the WHC Program will reimburse for liquid-based cervical cytology (Pap tests). Below are the authorized CPT codes and their associated rates:

88142	Cytopathology (liquid-based Pap test) cervical or vaginal, collected in preservative fluid, automated thin layer preparation; manual screening under physician supervision	$28.31
88143	Cytopathology, cervical or vaginal collected in preservative fluid, automated thin layer preparation; manual screening and rescreening under physician supervision	$28.31
88174	Cytopathology, cervical or vaginal, collected in preservative fluid, automated thin layer preparation; screening by automated system, under physician supervision	$28.31
88175	Cytopathology, cervical or vaginal, collected in preservative fluid, automated thin layer preparation; screening by automated system and manual rescreening, under physician supervision	$28.31

Criteria
A liquid-based Pap test is a procedure in which cells are scraped from the cervix for examination under a microscope. The cells are rinsed into a small container of liquid. The cells are then placed onto slides and examined under a microscope for evaluation. The liquid-based Pap test has a higher sensitivity and lower specificity than conventional Pap tests; more false positives will result when using this type of Pap test. Women with positive test results must receive a full diagnostic workup to distinguish the true positives from the false positives. The American Cancer Society and the American College of Obstetricians and Gynecologists support every two-year cervical cancer screening with liquid-based Pap testing as long as the results are normal and the woman is not immunocompromised or does not have a history of prenatal exposure to diethylstilbestrol (DES).

Schedule for Cervical Screening with Liquid-Based Pap Tests with Normal Results

The WHC Program will reimburse every other year for cervical cancer screening with liquid-based Pap tests for women who have an intact cervix or for women who have had a hysterectomy due to cervical neoplasia. Due to the enhanced reliability of the liquid Pap test, the every other year interval schedule is an important mechanism both for protecting women from false positives and all that they entail and for ensuring that the greatest number of women can be screened with limited WHC Program resources.

When a woman has had three consecutive, normal cervical cancer screening tests documented within a 60-month period, the screening interval shall increase to once every three years. To calculate the time period for the three normal screening tests, the first test date should be considered "month 0," the second test would occur around month 24, and the third around month 48. Thus, the woman has a liquid-based Pap test every two years in keeping with the biennial recommendation. The frequency of performing cervical cancer screening changes to every three years once she has had three consecutive, normal cervical cancer screening tests.

Providers must review a woman's prior Pap test results before performing a Pap test. If the woman has had three consecutive normal Pap tests in a 60-month period, she must convert immediately to the every three-year screening policy.

Schedule for Cervical Screening with Liquid-Based Pap Tests with Abnormal Results

If a woman receives an abnormal screening test result at any time, the appropriate diagnostic workup must be completed within 60 days from the date of the abnormal Pap test.

In the instance of abnormal results, some providers will choose to follow a woman's clinical progress by repeating the Pap test at more frequent intervals, such as every 6 months not to exceed a 24-month period. This is a legitimate circumstance following a diagnostic workup in which a liquid-based Pap test may be reimbursed more frequently than every 2 years. When a woman's post-diagnostic workup frequency recommendation has been completed, she will resume the periodic screening intervals outlined in this policy.

Reimbursement Process

When performing a liquid-based Pap test, indicate on the lab slip the appropriate test to be performed such as:

- Liquid Based GYN Cytology Only (CPT Code is 88142): indicates only a Pap test will be performed.
- Liquid Based GYN Cytology with reflex to High-Risk HPV when ASC-U (CPT Code is 88142 and 87621): indicates Pap test and HPV DNA only if Pap test is ASC-U.
- Liquid Based GYN Cytology with HPV DNA (CPT Code is 88142 and 87621): indicates Pap test and HPV DNA regardless of Pap test result. This is only reimbursable for management of successful LSIL diagnostic workup post colposcopy.

Conventional Pap Test

In accordance with the designated schedule, the WHC Program will continue to reimburse for conventional cervical cytology (Pap tests) at the Medicare allowable rate. Following are the allowable CPT codes and their associated rates:

88164	Cytopathology (conventional Pap test), slides cervical or vaginal reported in Bethesda System, manual screening under physician supervision	$14.76
88141	Cytopathology (conventional Pap test), cervical or vaginal, any reporting system, *requiring interpretation by physician*	$23.56

Schedule for Cervical Cancer Screening with Conventional Pap Test

The WHC Program will reimburse on an annual basis for cervical cancer screening with conventional Pap tests for women who have an intact cervix or for women who have had a hysterectomy due to cervical neoplasia. When a woman has had three consecutive, normal cervical cancer screening tests documented within a 60-month period, the screening interval shall increase to once every three years.

Providers must review a woman's prior Pap test results before performing a Pap test. If the woman has had three consecutive normal Pap tests in a 60-month period, she must convert immediately to the every three-year screening policy.

Schedule for Cervical Screening with Conventional Pap Tests with Abnormal Results

If a woman receives an abnormal screening test result at any time, the appropriate diagnostic workup must be completed within 60 days from the date of the abnormal Pap test.

Exception to Every Three Year Cervical Cancer Screening

The following conditions illustrate exceptions to converting women to the every three years cervical cancer screening interval:

- Immunocompromised women;
- Women with a history of prenatal exposure to DES (diethylstilbestrol); and
- Women with a history of cervical cancer. These women should remain at annual or every two years screening depending upon the type of screening technology performed.